Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P229203PC-La	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/DE2003/003702	International filing date (*day/month/year*) 05 November 2003 (05.11.2003)	Priority date (*day/month/year*)
International Patent Classification (IPC) or national classification and IPC C07D 491/14, A61P 35/00		
Applicant SALAMA, Zoser, B.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 8 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand 21 December 2004 (21.12.2004)	Date of completion of this report 16 August 2005 (16.08.2005)
Name and mailing address of the IPEA/EP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/DE2003/003702

I. Basis of the report

1. With regard to the elements of the international application:*

☐ the international application as originally filed

☒ the description:
pages 1-36, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☒ the claims:
pages _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages 1-39, filed with the letter of 01 April 2005 (01.04.2005)

☒ the drawings:
pages 1/10-10/10, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

*** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/DE2003/003702

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☐ claims Nos. 6-26, 39

because:

☒ the said international application, or the said claims Nos. 5-26, 39 relate to the following subject matter which does not require an international preliminary examination *(specify)*:

SEE ADDITIONAL SHEET

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: BOX III.1

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. Claims 6-26 and 39 relate to subject matter which, in the opinion of the Examiner, falls under PCT Rule 67.1(iv). Consequently, no opinion is formed on the industrial applicability of the subject matter of these claims (PCT Article 34(4)(a)(i)).

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-39	YES
	Claims		NO
Inventive step (IS)	Claims	1-39	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-5, 27-38	YES
	Claims	6-26, 39	NO

2. Citations and explanations

1. WO 02/092085 A (CHAE SOO-WAN; EUN JAE-SOON (KR); JUNG YOUNG HOON (KR); KIM DAE-KEUN), 21 November 2002 (2002-11-21) (D1) discloses on page 7 the compound 4, and on page 1, lines 5 and 6, its use in general terms in pharmaceutical mixtures.

GRYNKIEWICZ G ET AL: "Synthesis and biological activity of O-acyl and O-alkyl chelidonine derivatives", EUROPEAN JOURNAL OF MEDICINAL CHEMISTRY, EDITIONS SCIENTIFIQUES ELSEVIER, PARIS, FR, Vol. 36, No. 11-12, November 2001 (2001-11), pages 951-960, XP004400915, ISSN: 0223-5234 (D2) discloses on page 953 the compound 3a and in the abstract its use in pharmaceutical mixtures.

Since the above-mentioned compound was deleted from the original claims, the subject matter of the present claims 1-5 and 38 is novel (PCT Article 33(2)).

2. The chelidonine acetate disclosed in D1 and D2 is not described therein as an antitumoral agent, but rather as an anti-arrhythmic agent (D1) or in its effect upon the central nervous system (D2).

Consequently, a person skilled in the art seeking for antitumoral agents would not fall back upon D1 or D2 or modify the compounds described therein with any reasonable hope of success.

The subject matter of the present claims 1-5 and 38 can therefore also be regarded as being inventive (PCT Article 33(3)).

3. The subject matter of the present claims 6-26 and 39 cannot be found in the prior art (PCT Article 33(2)) because chelidonine acetate is not described as an antitumoral agent in D1 and D2, which represent the structurally closest prior art. Moreover, the applicant was also able to demonstrate the effectiveness of said compounds, and therefore both novelty (PCT Article 33(2)) and inventive step (PCT Article 33(3)) can be recognised in the present claims 6-26 and 39.

4. In the PCT Contracting States, there are no uniform criteria for assessing the industrial applicability of Claims 6-26 and 39 in their present form. Patentability can also depend on the wording of the claims. The EPO, for example, does not recognise the industrial applicability of claims to the use of a compound in a medical treatment; it does, however, allow claims to the first use of a known compound in a medical treatment or to the use of such a compound in the manufacture of a drug for a new medical treatment.

5. Pursuant to PCT Rule 5.1(a)(ii), D1 and D2 should be acknowledged in the description.